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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,355	07/18/2003	John Paul Mizzer	DCS-9129	5039

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DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,355	MIZZER ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-28-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2006 has been entered.

2. The amendment filed December 28, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the changes to paragraphs 23, 27 and 29-30 are not fully supported by the original specification. Applicant has made substantial changes to claims 23 and 29-30 in particular without showing the basis for the changes made. While there is a general statement that the changes are supported applicant has hot pointed to specific portions of the original disclosure as the basis for the additions made. It is also noted that the applicant failed to indicate the changes as required for amendments to the specification. It appears that applicant is trying to place language into the specification that addresses examiner's concerns related to the written description/enablement without clear basis in the original specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method requires that the reagent addition resources be initially throughput limiting and the other assay resources to be capable of handling more assay throughput. This places a requirement that these other assay resources be provided in such a manner that they can interact with the additional reagent resources to increase the throughput. The instant specification is extremely scarce on description

of how the other assay resources are capable of handling the ability to add reagents at two or three positions around the reaction ring and increase the throughput. As an example examiner would like to look at an instrument that performs only a single assay using a single reagent. In such a situation the time for each operation appears to be set at 3.6 seconds. Examiner acknowledges that movement of the turntable by a larger amount between each dispensing operation and placing the additional reagent resources at locations with respect to the plural analyzers is within the skill of one of ordinary skill in the art. However, applicant has not provided an explanation of how the sample dispenser and the washing mechanism are not throughput limiting. Being able to place reagent in two or three samples after the addition of additional reagent resources compared to the one sample prior to the addition of additional reagent resources, means that the sample dispense has to be capable of dispensing two or three samples in the same amount of time as previously allowed to dispense one sample. As far as the washing section goes, it also has to wash two or three reaction vessels in the time/space that it previously had for each vessel. The specification fails to provide details of how this can be met and still provide the cleaning capability when only one reagent was dispensed during each operation. When one increases the number of reagents or reagents per assay that are capable of being dispensed, one only increases the requirements/complexity that the other resources must be capable of handling including different reaction times and different types of assays. For example, if one is using an endpoint assay, a minimum time is required to perform the assay and the minimum time may vary between assays. When this is compared with a rate type of assay that requires a specified time between when the reagent is added and the determination is performed, it is clear that different assays place different requirements on a system and applicant has not described how the additional resources can be con figured to meet these varied needs even for a single reagent that requires a single reagent. It is not clear if there would be modifications to the other resources that would be required to handle the extra reagent dispensing capacity. Thus the invention is much more complex that simply adding additional reagent capacity and applicant has not provided an enabling disclosure. While original paragraph [0030] states that the full number of available cuvette ports is under utilized and the original abstract would seem to point to the number that are not available before the addition of additional reagent resources is 50%, there is no description of how the device is configured so that this is the case.

The following is being repeated because it still applies to the instant claims. Examiner has been looking at the example given and determined that either there are additional changes that applicant has either not disclosed or the data in at least tables 2 and 3 are incorrect. Looking at the information of paragraph [0028] it is clear that for each operation (cuvette rotation and dwell time) 3.6 seconds are required. This leads to a maximum of 1000 operations/reagent additions per hour. It is noted that the application does not teach how to increase this number. It is not clear how a second or third reagent is added when more than one reagent is required to perform an assay. Possibilities include the cuvettes being prevented from rotating so that the second and/or third reagents are added before the cuvettes are rotated or the second and third reagents are added after the cuvette has made at least one complete rotation. It appears that for the example applicant only considered situations in which all of the analyses being concurrently performed on the analyzer required the same number of reagent additions and a single rotation of the cuvette to complete the assay after the addition of all the required regents. In this instance, examiner can see how the throughput data of table 1 was obtained. Table 2 is after the addition of a second reagent storage area and a second reagent addition and dispense arm. The paragraph bridging pages 10-11 does not indicate that any additional changes were made to the instrument. In this case, 3.6 seconds are required for each operation and the maximum number of assays per hour is still 1000. Thus the throughput for a single reagent required is still 1000 since it does not matter which of the aspirate and dispense arms adds the single reagent. Thus the throughput is only increased by addition of the second reagent storage area and the second reagent addition and dispense arm when assays requiring two or three reagents are being performed. From this it is clear that the throughput data for a single required reagent in table 2 is not correct. The only change described in the paragraph bridging pages 11-12 is the addition of a third reagent storage area and a third reagent addition and dispense arm. As noted above, without additional changes to the instrument, 3.6 seconds are required for each operation and the maximum number of assays per hour is still 1000. Thus the throughput for assays requiring one or two reagents is only 1000 since it does not matter which of the aspirate and dispense arms adds the reagent(s). Thus the throughput is only increased by addition of the third reagent storage area and the third reagent addition and dispense arm when assays requiring three reagents are being performed. From this explanation it is clear that the throughput data for one or two required reagents in table

3 are not correct. Essentially what the example shows is that if the assays being run require more than one reagent to be added, the throughput for these assays can be increased or the analyzer can continue to run at its maximum rate for a single required reagent by adding one or more modules that provides the capability of adding multiple reagents at the same time. The application fails to teach how to increase the capacity to reach a throughput of more than 1000 assays/hour by adding reagent resources in an incremental manner. Even if one takes into account that the abstract says that prior to addition of the additional reagent resources, only 50% of the cuvette ports were utilized, there is no disclosure of how the remaining cuvette ports are utilized with the addition of the additional reagent resources. Even if examiner looks at 50% of the cuvette ports present and unused when only the original reagent resources were present, the data of table three is not possible to be obtained since there is not sufficient available excess capacity to allow 3000 samples to be run. The disclosure also does not teach if those added reagent resources are limited to a single reagent, a set of reagents different from those initially present, a duplication of those originally present or some combination. Because of this, the claims will be treated for examination purposes as covering the addition of incremental capacity as demand increases (to perform new assays or the addition of capacity to add multiple reagents simultaneously).

5. Claims 3-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the initially configured reagent resources is required to contain all of the reagents necessary to perform all of the assays in the group or if only a portion is necessary to meet the claim. It is also not clear if the added regent resources is a duplicate of the initial reagent resources, a subset of the original resources or contains one or more regents that are different from the initial reagent resources. For examination purposes the claims are being treated as not requiring the initial reagent resources to contain all of the reagents necessary to perform the assays of the group.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 3-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (US 3,615,239). In the patent Jones teaches an automated analyzer and its programmer. The analyzer has three parts, a transporter unit (A), a delivery unit or system (B) and the programming means(C). Column 2, lines 12-19 teach that the programming means is constructed in modular form, each module being representative of a single test or operation to be performed by the analyzer. Therefore, where the number of diagnostic tests to be performed by the analyzer is to be increased at some later date after installation of such a unit, it is a relatively **simple matter to add a further module for programming the analyzer to perform the additional test**. Column 4, lines 6-19 teach that a wide variety of tests may be performed, in general such tests require **the addition of one or more reagents to the sample**, a mixing of the reagents and the sample fluid, a period of incubation during which the test reaction may occur, and a final photometric analysis of the reaction mixture. In the apparatus disclosed, five treatment stations (26-30) are indicated ***although a greater or smaller number may be provided depending on the number and type of different diagnostic tests to be performed***. At each of these stations, a predetermined quantity of a test reagent may be introduced into selected sample tubes from a suitable source of supply, one such source being indicated schematically at 31. Column 4 also describes the structure to add reagents at each station. In discussion the programming means, the first two paragraphs of column 7 further emphasize that the number of control modules and also the number of deliver stations depend on the size of the analyzer and the number of different treatment procedures to be performed.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 3-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berglund (US 4,459,265) or Minekane (US 4,906,433) in view of Jones as described above.

In the patent Berglund teaches an analysis apparatus in which one or, preferably, a plurality of reagent dispensing stations (R1-R3) are placed around a conveyor means. Column 2 lines 21-28 teach that the objective is to provide an apparatus that is relatively inexpensive, is of simple construction, requires a relatively small space and can be programmed to carry out a large number of different analyses on a larger number of samples which are supplied to the apparatus simultaneously. From the first full paragraph of column 3, the one or preferably a plurality of reagent-supply stations, capable of selectively supplying a plurality of different reagent liquids to the reaction tube advanced by the stepwise drivable conveyor or rotatable turntable, can supply each separate sample a large number of different reagent liquids and combinations thereof, thereby enabling the apparatus to carry out a large number of different analyses, by programming the reagent-supply stations to select a reagent liquid in dependence upon the desired analysis. Since each reagent-supply station only requires a single metering pump, the apparatus is of relatively simple construction and inexpensive, despite the large number of different analyses which can be carried out. The last paragraph of column 10 teaches that the apparatus can be modified and designed in a number of different ways, to suit the intended purpose. For example, the number of different reagent-supply stations, their mutual positions, and their positions relative to the positions of the sample-supply stations can be varied. Additionally, the number of possible reagent liquids in each reagent-supply station and the number of tubes on the turntable capable of being supplied by the reagent-supply station may be varied. Berglund does not teach modular configuration for the additional reagent-supply stations.

In the patent, figure 1 is a conventional automatic analyzer having a single reagent supply position. The first two full paragraphs of column 2 teach that due to the increasing amount and types of analyses being performed the number of reagents required is causing the reagent storage space to become expansive and the speed of the analyzer to become slowed by the time required

to bring the reagent into a position that it can be withdrawn. The next paragraph teaches that the object is to allow the analyzer to perform high speed analysis regardless of the number of items to be analyzed and the quantities of reagent required for the analysis. This is accomplished by providing a plurality of reagent storage locations and reagent distribution means as shown in figures 2 and 4. The last full paragraph of column 7 before the claims teaches that various modifications can be made to include the number and position of the reagent vessel storage locations. Minekane does not teach a modular configuration for the additional reagent storage and supply locations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a modular configuration as taught by Jones for the additional reagent-supply stations or Berglund or the additional reagent storage and supply locations of Minekane because as shown by Jones the modular configuration facilitates the variation of reagents as needed by the number and type of analyses to be performed and the teaching by both Berglund and Minekane that the respective reagent supply means can vary in number and configuration.

2. Applicant's arguments filed December 28, 2006 have been fully considered but they are not persuasive. The basic problem with the instant application is that while it does make statement that the other assay resources are under utilized, it does not teach how these other resources are configured so that they have excess capacity and how the instrument is configured to utilize that excess capacity with the addition of the additional regent resources. Additionally, the specification and claims are not clear when it comes to what reagents are contained in any of the reagent resources. While examiner can see that applicant might not like to limit the scope of the reagents in the various reagent resources, this places the above applied Jones reference within the scope of the instant claims. In response to the arguments, the example given has problems in either some of the changes made to increase throughput have not been disclosed or the tables do not properly reflect the conditions and in some instances throughput is not increased even though the table points to an increase. These are relevant to the anticipation by the Jones reference since the claims are not commensurate in scope with the arguments. Additionally as explained above, there are situations in which the addition of reagent resources also fails to increase the throughput of the example given. In the same way addition of additional reagent resources in Jones allows the analyzer to continue to operate at the maximum throughput in spite of the

different reagent needs for the assays being performed. In this way the teachings of Jones are equivalent to the example of the specification and therefore anticipate the claims. Relative to the obviousness rejections, the same response is applicable since the claims fail to define reasons for the increased demand, specific forms of the additional incremental capacity or the specific configuration of the analyzer.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional references relate to increasing throughput.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist
Primary Examiner
Art Unit 1743

Okay to enter QB 3/10/07

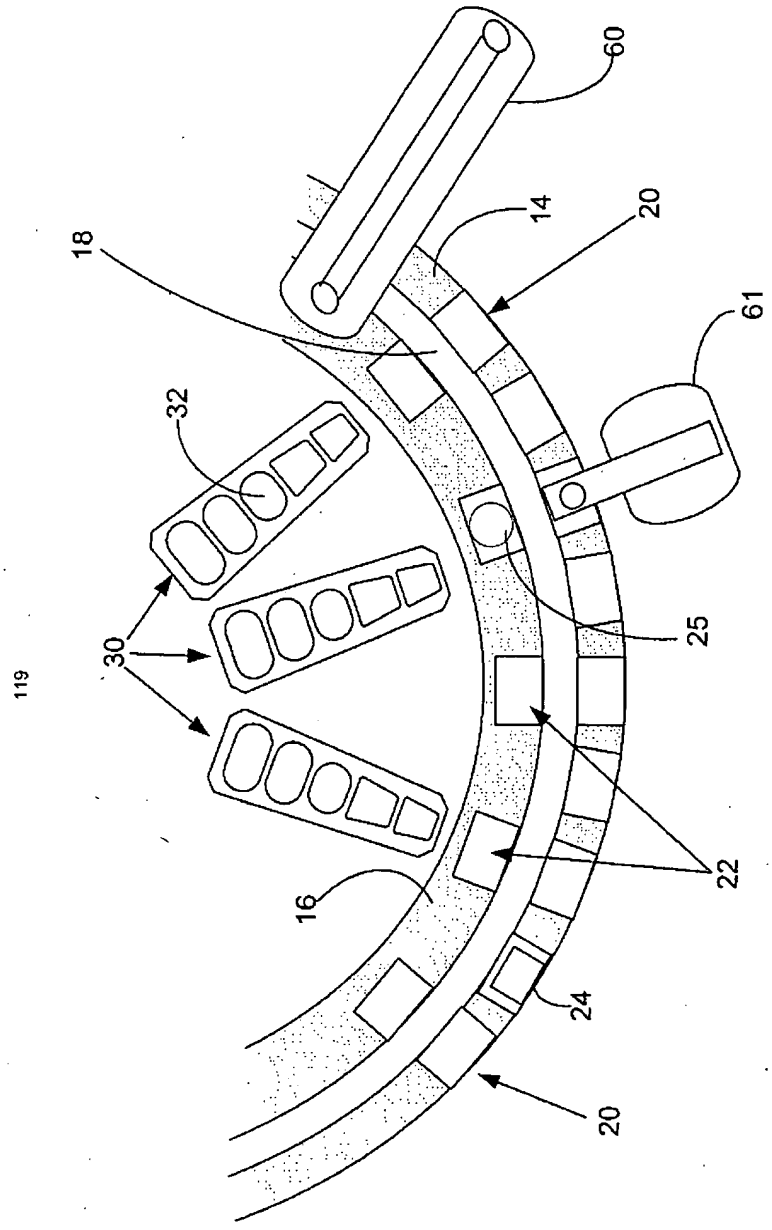

Fig. 2 PRIOR ART